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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,334	02/13/2002	Steven J. Soldin	64688/155	6011

7590 02/24/2004

Law Offices of Dr. Melvin Blecher
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EXAMINER	
GUPTA, ANISH	
ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SAM.

Office Action Summary	Application No.	Applicant(s)	
	10/073,334	SOLDIN, STEVEN J.	
	Examiner	Art Unit	
	Anish Gupta	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-8 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Note that claims 2-3 have been added to the rejection since they are dependant upon claim 1 and do not resolve the apparent indefiniteness with respect to derivatives as recited below.

Applicants argue, with regards to derivatives, that "[i]t is unreasonable to expect the applicant to know every possible derivative or metabolite of such a complex molecule that would be pharmacologically active, as to be able to recite in the claim every conceivable modification of the chemical structure that is biologically active."

In reviewing a claim for compliance with 35 U.S.C. § 112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. § 112, second paragraph by providing clear warning to others as to what constitutes infringement of the patent. See Solomon v. Kimberly-Clark Corp., 216 F.3d 1372, 1379, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000). If the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement, a rejection of the claim under 35 U.S.C. § 112, second paragraph would be appropriate. See Morton Int'l, Inc. v. Cardinal Chemical Co., 5 F.3d 1464, 1470, 28 USPQ2d 1190, 1195 (Fed. Cir. 1993).

Here, if Applicants themselves do not know every possible derivative or metabolite of a such a chemical complex, then they have not adequately given notice to one of ordinary skill in the art as to the metes and bounds of the claims. That is to say, if Applicants themselves do not know the numerous permutations that could qualify as derivatives, how can one of ordinary skill in the art understand how the avoid infringement? The language is clearly such that a person of ordinary skill in the art cannot interpret the metes and bounds of the claim so as to understand how to avoid infringement and a rejection of the claim under 35 U.S.C. § 112, second paragraph would is appropriate.

For this reason, the rejection is maintained.

Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-8 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Note that claims 2-3 have been added to the rejection since they are dependant upon claim 1 and do not resolve the apparent lack of written description with respect to derivatives as recited below.

Applicants comments regarding the peptides is acknowledged. Applicants are wholly correct that FK-506 and rapamycin are unrelated to peptides. Even with this, the specification lack proper written description for FK-506 derivatives for the reasons set forth below.

Applicants argue that the specification has provided written description for metoblites and derivatives of the FK-506 and rapamycin. Applicants make reference to page 2 and 12 to provide ample support for describing "sixteen (16) known metabolites or rapamycin," metabolites of Fk-506 and "five (5) pharmacologically active derivatives of rapamycin."

It is acknowledged that the specification provides written description for derivatives of rapamycin and metabolites of FK-506 and rapamycin. However, the specification fails to describe any compounds that would be derivatives of FK-506. Applicants arguments are isolated to derivatives of rapamycin and metabolites of FK-506 and rapamycin and do not discuss the derivatives of FK-506. The specification still lacks written description for what compounds constitute derivatives of FK-506. The possible variations are limitless since any modification in the compound can qualify it as a FK-506 derivative. The ability of such a compound to bind to the immunophilin does not provide sufficient written description for the derivative. Thus, unlike Applicants contention, the standards as to the number of examples sufficient to establish a genus has not been exceed since the specification does not provide any number of compounds that qualify as FK-506 derivatives.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 8 remains rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,410,340. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The rejection of claims 1, 4-7 is withdrawn in light of Applicants arguments. However, claims 8 remains rejected for the reasons set forth below.

For claim 8 Applicants argue that the claim has been amended to recite recombinant 8.4kDa immunophilin and thus is distinguished over the US Patent.

However, applicants must not forget, that when dealing with product claims the product is not limited by the process of making. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Here, even though the immunophilin is produced by recombinant means, it remains the same immunophilin. When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not. Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the

characteristics of the claimed product. Applicants have not met their burden that the product produced by recombinant means is significantly different than that isolated from the cytoplasm.

The rejection of claim 8 is maintained.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback , can normally be reached on (703)306-3220. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

2/10/04

Anish Gupta
Patent Examiner